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(54) Title: PERCUTANEOUSLY IMPLANTABLE MEDICAL DEVICE CONFIGURED TO PROMOTE TISSUE INGROWTH

(57) Abstract: An implantable device including a housing having a stud projecting percutaneously through an incision in the patient's skin. The stud defines a peripheral surface extending longitudinally inwardly from the stud outer end. The longitudinal peripheral surface is used as a substrate to carry a peripheral fibrous layer which extends longitudinally along the stud from its outer end adjacent to the skin incision to below the patient's epidermal and dermal skin layers for promoting laterally directed soft tissue ingrowth. The housing also defines a lateral shoulder surface oriented substantially perpendicular to the longitudinal peripheral surface. The shoulder surface, when implanted, is located just inwardly from the patient's outer skin surface. The shoulder surface also carries a porous layer conducive to promoting tissue ingrowth. The provision of both lateral and longitudinal porous layers on the device allows tissue ingrowth, i.e., tissue growth into the interstices of both porous layers to form an enhanced infection resistant barrier while also providing improved device anchoring.

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**TITLE: PERCUTANEOUSLY IMPLANTABLE MEDICAL DEVICE
CONFIGURED TO PROMOTE TISSUE INGROWTH**

FIELD OF THE INVENTION

5 This invention relates generally to medical devices intended to be surgically implanted in a patient's body. More particularly, the invention is directed to an implantable percutaneous device, and method of implantation, especially configured to promote soft tissue ingrowth for creating an infection resistant barrier and for anchoring the implanted device in place.

10

BACKGROUND OF THE INVENTION

It is generally known that a porous outer surface can be used on an implantable medical device to promote bone ingrowth to facilitate device anchoring. It has also been suggested that the application of a porous surface to a percutaneous implantable device can be helpful for promoting tissue ingrowth. For example, see European Patent Publication 0367354B1 published 09.05.90 entitled "A percutaneous implant". It is also noted that so called "dacron cuffs" have been used to accommodate tissue ingrowth for anchoring percutaneous catheters.

20

SUMMARY OF THE INVENTION

The present invention is directed generally to medical devices and more particularly to a structural configuration and method of implantation for promoting tissue ingrowth around a percutaneously projecting portion, or stud, of the medical device so as to create an infection resistant barrier, provide effective anchoring and inhibit marsupialization (which reduces vascularization of the local tissue).

25

An implantable device in accordance with the invention includes a housing having a projecting stud defining an outer end and a peripheral surface extending longitudinally inwardly from said outer end. A longitudinally extending porous peripheral layer is formed on the peripheral surface characterized by a porosity conducive to promoting tissue ingrowth. When the device is implanted, the stud projects through a skin incision and places the porous peripheral layer adjacent to the skin surrounding the incision. The

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device is intended to be implanted so that the porous layer is oriented substantially perpendicular to the patient's skin plane adjacent to the incision site and extends longitudinally below the skin surface.

5 A porous layer in accordance with the invention is preferably formed by mounting a layer of fibrous material on the projecting stud of the implantable device housing. The fibrous layer is preferably fabricated from bio compatible metallic materials, such as titanium, nitinol, silver, or stainless steel, or from polymeric materials, such as polyolefins, Teflon, nylon, Dacron, or silicone. Fibers can be wound directly onto the housing stud or alternatively a separate structure (e.g., mesh or sintered polymeric or metallic material) can be fabricated and then attached to the stud using mechanical or adhesive techniques. To adequately promote soft tissue ingrowth, the resulting fibrous layer should preferably contain pore sizes on the order of 50 to 200 microns with a porosity of 60 to 95%.

10 A preferred implantable device in accordance with the invention includes a housing having a stud projecting percutaneously through an incision in the patient's skin. The stud defines a peripheral surface extending longitudinally inwardly from the stud outer end. The longitudinal peripheral surface is used as a substrate to carry the aforementioned fibrous layer. The peripheral fibrous layer is located so that when implanted, it extends to below the patient's epidermal and dermal skin layers for promoting laterally directed soft tissue ingrowth.

15 In accordance with the invention, the housing also defines a lateral shoulder surface oriented substantially perpendicular to the longitudinal peripheral surface. The shoulder surface, when implanted, is located just inwardly from the patient's outer skin surface. The shoulder surface also carries a porous layer conducive to promoting tissue ingrowth. The provision of both lateral and longitudinal porous layers on the device allows tissue ingrowth, i.e., tissue growth into the interstices of both porous layers, to promote vascularization and form an enhanced infection resistant barrier while also providing improved device anchoring.

20 Moreover, it may sometimes be desirable to selectively incorporate appropriate substances into, or adjacent to, the porous layers for various medical reasons such as promoting tissue healing and infection resistance

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and inflammation. Such substances are known in the literature and include, e.g., antibiotics, silver compounds, and steroid based agents.

Embodiments of the invention can be advantageously used with a wide variety of medical devices adapted for percutaneous implantation. By way of
5 example, such devices include implantable hearing aids which can percutaneously project into the ear canal and catheters, cables, and/or sensors which can project percutaneously to provide access to various internal sites, e.g., access to the abdominal cavity, to the inner eye, to the circulatory system, etc.

10

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 schematically depicts an exemplary medical device (i.e., a hearing aid, percutaneously implanted in a patient's ear canal) which can advantageously utilize the teachings of the present invention;

15 Figure 2 is an enlarged schematic representation showing a conventional medical device penetrating the epidermis and dermis skin layers shortly after implantation;

Figure 3 is a schematic representation similar to Figure 2 showing skin downgrowth around the conventional medical device typically occurring after
20 implantation;

Figure 4 schematically shows part of a device housing having a portion, or stud, adapted to project percutaneously in accordance with the invention having longitudinally and laterally extending surfaces for respectively supporting porous layers;

25 Figure 5 is a side sectional view of the device housing of Figure 4 also showing an optional end cap;

Figure 6 is an enlarged schematic representation of a fibrous mesh which can form a porous layer in accordance with the invention;

Figure 7 is similar to Figure 5 but additionally represents the inclusion
30 of an optional supplemental agent for cooperating with the porous layer to promote tissue healing and/or resist infection and inflammation;

Figure 8 is a schematic representation similar to Figure 3 but representing tissue ingrowth into the interstices of longitudinal and lateral porous layers in accordance with the present invention;

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Figures 9A-9D illustrate various configurations showing the use of a transitional surface installed on a housing stud to beneficially modify healing;

Figure 10 schematically depicts the use of an invention embodiment in a vascular application where a catheter, cable, or sensor extends
5 percutaneously through the patient's skin layers;

Figure 11 schematically depicts the use of an invention embodiment in an ocular application for providing access to the inner eye via a percutaneous catheter, cable, or sensor;

Figure 12 is an isometric view of one preferred embodiment of the
10 invention intended for implanting adjacent to a patient's ear canal to promote hearing (as generally depicted in Figure 1); and

Figures 13A, 13B, and 13C respectively show top, side, and end views of the device of Figure 12.

15

DETAILED DESCRIPTION

Attention is initially directed to Figure 1 which schematically depicts an exemplary application of the teachings of the invention. Figure 1 represents a fragmentary front view of a patient's head 20 (i.e., as seen when looking at the patient's face) showing the patient's ear 22, pinna 24 (sometimes referred to as "auricle"), and an ear canal 26. The soft tissue space behind the pinna
20 24 is often referred to as the retro-auricular space or cavity 28.

Figure 1 also depicts a generic hearing aid 30 implanted within a recess 32 behind the patient's ear canal 26. The recess 32 can be readily formed by a relatively simple surgical procedure involving for example,
25 tunneling through the space 28. The recess nominally extends from a proximal end 36 to a distal end 38 located at an incision site 40 opening into the ear canal 26. The hearing aid 30 depicted in Figure 1 is comprised of a generally elongate, e.g., cylindrical, tubular housing 42 having a proximal end 44 and a distal end 46. The housing 42 is preferably formed of a
30 biocompatible material, e.g., titanium.

The tubular housing 42 typically contains electronic circuitry for driving a sound generator, i.e., an electroacoustic transducer (not shown) located within the housing proximate to the distal end 46. The housing distal end, as shown in Figure 1, preferably projects percutaneously through the incision site

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40 into the ear canal 26 to locate the transducer in or immediately adjacent to the ear canal.

Figure 2 schematically depicts the housing distal end 46 in greater detail generally showing the formation of the patient's skin layers 50 (i.e., dermis 54 and epidermis 56) adjacent to the incision site 40, shortly after implantation of the housing 42. Figure 3 schematically illustrates how, in a typical prior art implantation, the epidermis 56 and other tissue layers, over a period of time, can grow downwardly along the longitudinal surface 58 of the housing 42. This tissue downgrowth, as depicted in Figure 3, tends to produce sinus tracts 59, susceptible for infection. Continued downgrowth can lead to marsupialization and ultimately can result in expulsion of the implant, e.g. hearing aid 30, from the patient's body.

The present invention is directed primarily to means for creating an infection resistant barrier around the housing distal end 46 at the percutaneous penetration, i.e., incision, site 40 in order to effectively anchor the implanted device and avoid the aforementioned problems associated with tissue downgrowth. Briefly, the infection resistant barrier is formed by promoting tissue ingrowth into a porous layer(s) formed on orthogonal (longitudinal and lateral) surfaces of the housing 42.

Attention is now directed to Figures 4 and 5 which illustrate a preferred manner of configuring the housing distal end 46 in accordance with the present invention. As shown, the housing 42 includes a lateral shoulder 60 which forms a reduced diameter stud 62 extending longitudinally therefrom and terminating at outer end surface 64. The stud 62 defines a longitudinally extending peripheral surface 66. The peripheral surface 66 typically has a circular cross section but other cross sectional shapes, e.g., oval, hexagonal, etc. can be used. Moreover, although, the outer end surface 64 is shown as being flat, in certain applications, it is preferable that the end surface have a different profile, e.g., conical or spherical.

In accordance with the invention, a first porous layer, or surface, 70 is formed along a longitudinally extending portion of the peripheral surface 66. The porous layer 70 is preferably formed by a mesh 72 of intersecting fibers 74 as depicted in Figure 6. The fibers can be of any suitable biocompatible material such as a metal, e.g., titanium, nitinol, silver, or stainless steel or a

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polymeric material, e.g., polyolefins, Teflon, nylon, Dacron, or silicone. The mesh 72 is preferably formed by cross winding the fibers 74 in multiple layers to define a porosity conducive to promoting tissue ingrowth, e.g., with pore sizes within a range of 50 to 200 microns and having a porosity of 60 to 95%.

- 5 The resulting porosity of the mesh 72 is a function of several factors including the diameter of the fibers 74 and the spacing between adjacent fibers.

- The mesh 72 can be formed by directly winding the fibers 74 on the peripheral surface 66 acting as a substrate. Alternatively, the mesh 72 can be formed as an integral structure and then attached to the peripheral surface 66
10 by suitable mechanical or adhesive means. As an alternative to winding the fiber mesh 72, a porous surface 70 can be formed by a sintered mass of metal or polymeric material having the aforementioned porosity characteristics.

- In accordance with the invention, as seen in Figure 5, a second porous
15 layer, or surface, 80 is provided oriented substantially perpendicular to the longitudinally extending porous surface 70. The porous layer 80 is formed on the laterally oriented surface 82 formed by shoulder 60. The porous layer 80 is preferably formed by a disk 84 formed of porous material having a central aperture for passing stud 62. The disk 84 can be adhered or mechanically
20 attached to the lateral shoulder surface 82. The disk 84 can be formed of a fiber mesh (Figure 6) or a sintered mass, as previously described, to provide porosity characteristics consistent with the previously mentioned porosity characteristics.

- Figure 8 illustrates the stud 62 percutaneously penetrating the patient's
25 skin layers 50 and shows how the soft tissue grows into the orthogonal porous layers 70 and 80 to create a closed infection resistant barrier around the stud. The ingrowth into the porous layers 70 and 80 additionally promotes vascularization as the dermis grows into and entwines with the mesh. It is also pointed out that Figure 8 demonstrates the use of an optional cap 86
30 adapted to be mounted on the stud outer end for protection of the tissue around the incision during the healing process.

It is pointed out that it is sometimes desirable to include one or more substances on the stud 62 to promote tissue healing and/or resist infection and inflammation. Suitable substances are known in the literature and

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include, for example, antibiotics, silver compounds, and steroid based agents. Such substances can be deposited on the stud 62 as shown in Figure 7, for example, as a sublayer 90 applied to the peripheral surface 66 beneath the porous layer 70. Alternatively, the substances can be incorporated within the mesh or sintered material of the porous layers 70 and 80.

Figure 9A depicts the device of Figures 4 and 5 but further shows the utilization of a transitional layer, or surface, 92 mounted on the stud peripheral surface 66 between the peripheral porous surface 70 and the stud outer end 64. The transitional surface 92 can have the same or a different porosity and/or composition as the porous surface 70 and can be variously configured as shown, for example, in Figures 9B, 9C, 9D. The transitional surface 92 is intended to beneficially modify the healing response of the adjacent tissue cells after implantation.

For convenience in explanation, the description thus far has mostly merely referred to a "stud" percutaneously projecting through the patient's skin layers. It should be understood that the term "stud" as used herein, is not intended to connote any particular structural configuration but rather to generically refer to any member percutaneously projecting from an orthogonal shoulder surface. In different applications, the stud can variously comprise a catheter, a cable, a sensor or other member which projects percutaneously from a lateral shoulder surface. Figure 10 depicts an exemplary application of the invention showing a catheter, cable, or sensor 94 which projects percutaneously for providing vascular access. Figure 11 depicts a further exemplary application where a catheter, cable, or sensor 96 projects percutaneously for providing access to the inner eye.

Attention is now directed to Figures 12 and 13A, 13B, 13C which depict a preferred embodiment 100 of the invention configured for use as a hearing aid in the manner schematically represented in Figure 1. The embodiment 100 comprises a housing 102 having a body portion 103 and a stud portion 104. The body 103 has a substantially rectangular (with rounded corners) cross-section (Figure 13A) defined by short sides 105 and long sides 106. The body extends longitudinally in a forward direction from a rear face 108 to a laterally oriented shoulder surface 110. The stud 104 extends forwardly from the shoulder surface 110 and terminates at a stud outer face 114. The

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body 103 houses electronic circuitry (not shown) for driving a sound generator, e.g., electroacoustic transducer (not shown), mounted in the stud proximate to the outer face 114. It is intended that when implanted, the stud 104 will project percutaneously to place the stud face 114 in the patient's ear canal.

As previously described, in order to promote healthy tissue ingrowth for anchoring the housing 102 and forming a bacteria resistant barrier, a porous layer comprising a first portion of porous material 116 is formed on the longitudinally extending peripheral surface 118 of stud 104 and a second portion of porous material 120 is formed on the laterally extending shoulder surface 110.

From the foregoing, it should now be appreciated that the application describes a method and apparatus for creating an enhanced infection resistant barrier around a percutaneously projecting member. Embodiments of the invention are useful in a wide variety of medical applications for creating an infection resistant barrier, for effective anchoring, and for avoiding the development of adverse conditions such as marsupialization. Although only a limited number of embodiments have been specifically described herein, it should be recognized that modifications, variations and other equivalent arrangements will occur to those skilled in the art coming within the spirit of the invention and the intended scope of the appended claims.

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CLAIMS

1. A medical device comprising:
a stud configured to project percutaneously outward through a patient's skin layers;
5 said stud defining an outer end and having a longitudinal peripheral surface extending inwardly from said outer end;
said peripheral surface having a longitudinal porous layer thereon for promoting soft tissue ingrowth;
a shoulder surface oriented substantially perpendicular to said stud peripheral surface and located inwardly from said stud outer end; and
10 wherein
said shoulder surface has a lateral porous layer thereon oriented substantially perpendicular to said longitudinal porous layer for promoting soft tissue ingrowth.
15
2. The medical device of claim 1 wherein at least one of said porous layers is characterized by a pore size within the range of 50 to 200 microns with a porosity of between 60 to 95%.
- 20 3. The medical device of claim 1 wherein at least one of said porous layers comprises a mesh of fibers.
4. The medical device of claim 1 wherein at least one of said porous layers comprises a mass of sintered material.
25
5. The medical device of claim 3 wherein said fibers are of metal material from within a group comprised of titanium, nitinol, silver, and stainless steel.
- 30 6. The medical device of claim 3 wherein said fibers are of polymeric material.

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7. The medical device of claim 4 wherein said mass is formed of metal material from within a group comprised of titanium, nitinol, silver, and stainless steel.

5 8. The medical device of claim 4 wherein said mass is formed of polymeric material.

9. The medical device of claim 1 wherein said stud carries means for promoting healing.

10 10. The medical device of claim 1 wherein said stud carries a sound generator and is configured to percutaneously project into a patient's ear canal.

15 11. The medical device of claim 1 wherein said stud comprises a portion of an implanted catheter providing access to an interior body site.

12. The medical device of claim 1 wherein said stud includes a sensor coupled to an interior body site.

20 13. The medical device of claim 1 further including a transitional layer mounted on said stud between said stud outer end and said longitudinal layer.

25 14. The medical device of claim 1 further including a cap configured for mounting on said stud outer end.

15. The medical device of claim 1 wherein said porous layers are formed of biocompatible material.

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16. A method of configuring an implantable medical device with a portion adapted to project percutaneously comprising the steps of:

providing a longitudinally projecting stud on said device having an outer end and a peripheral surface extending longitudinally inward from said outer end;

providing a laterally projecting shoulder surface on said device oriented substantially perpendicular to said stud peripheral surface; and

forming a porous layer on said stud peripheral surface and said shoulder surface conducive to promoting tissue ingrowth for establishing an infection resistant barrier.

17. The method of claim 16 wherein said step of forming a porous layer comprises forming the layer with a pore size within a range of 50 to 200 microns with a porosity of between 60 to 95%.

18. The method of claim 16 wherein said step of forming a porous layer comprises forming at least a portion of said layer with a fiber mesh.

19. The method of claim 16 wherein said step of forming a porous layer comprises forming at least a portion of said layer with a mass of sintered material.

20. The method of claim 16 wherein said porous layer is formed at least in part of metal material from within a group comprised of titanium, nitinol, silver, and stainless steel.

21. The method of claim 16 wherein said porous layer is formed at least in part of polymeric material.

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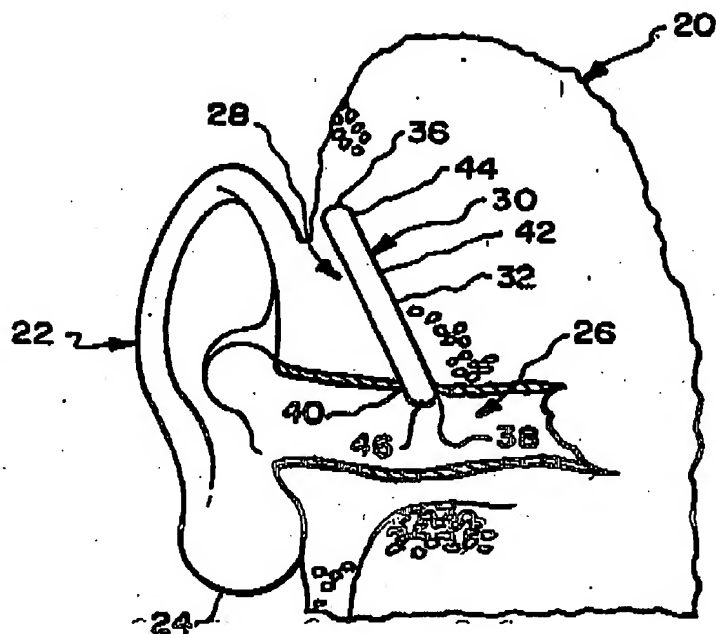


Figure 1

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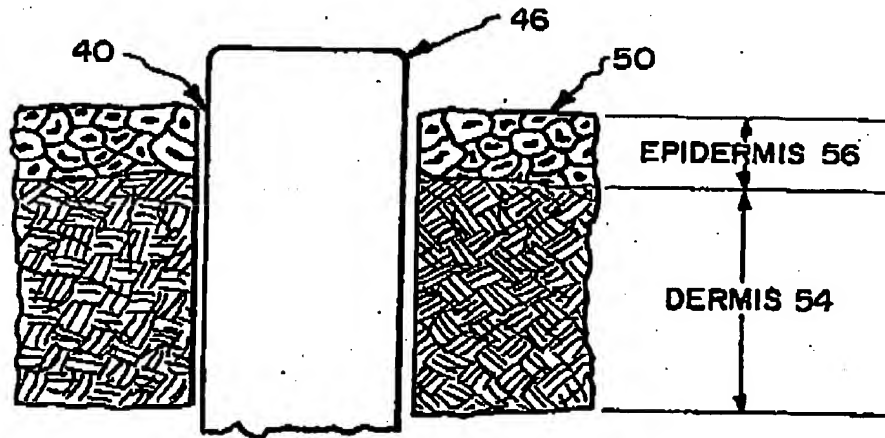


Figure 2

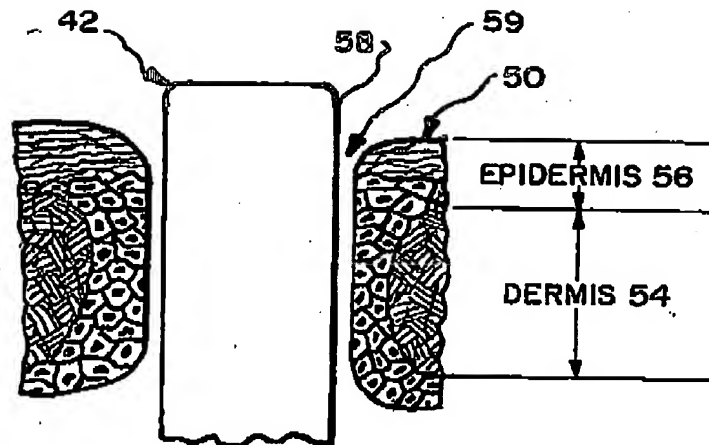


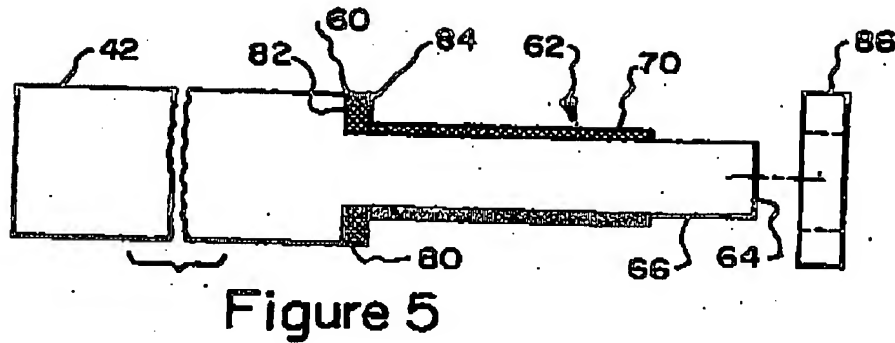
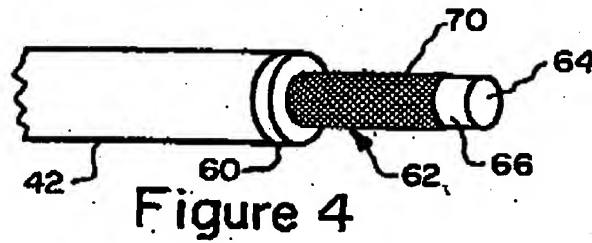
Figure 3

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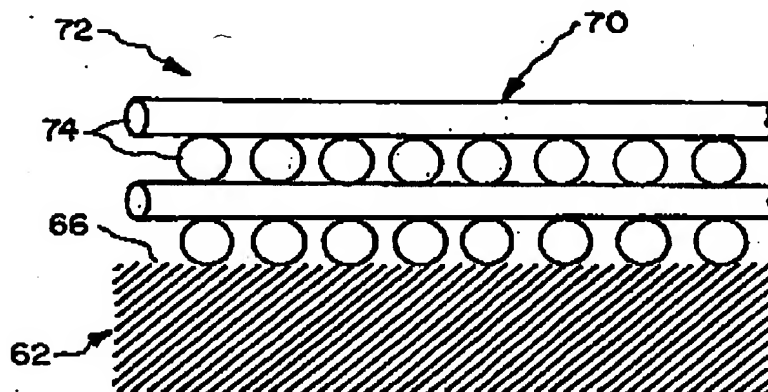


Figure 6

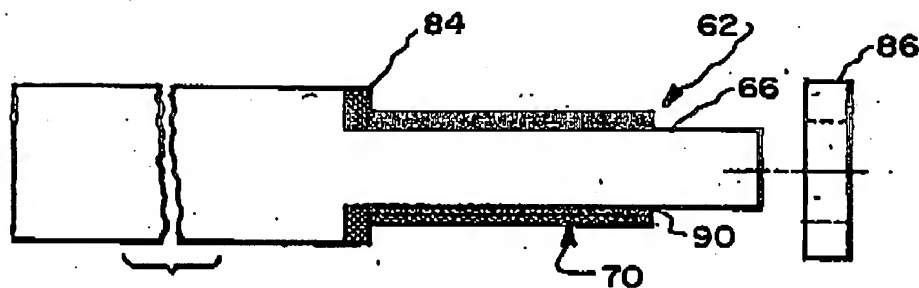


Figure 7

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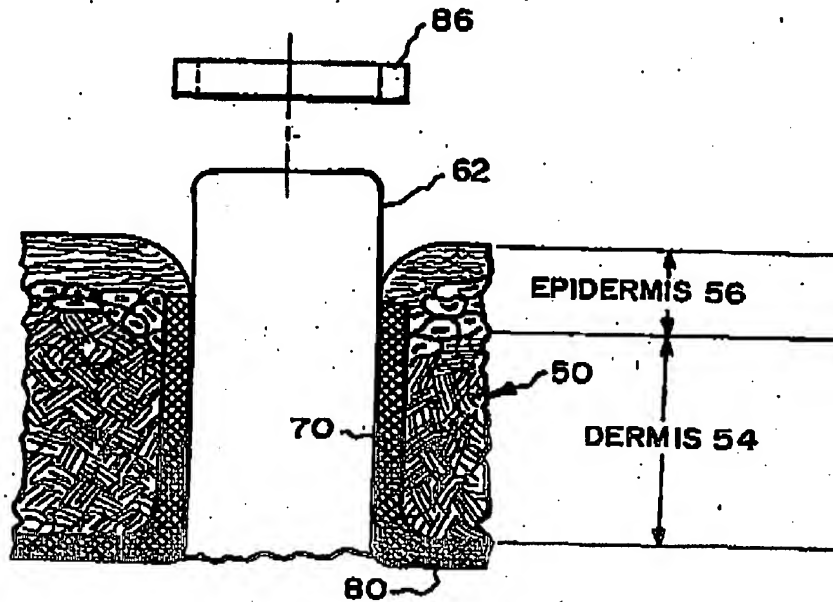


Figure 8

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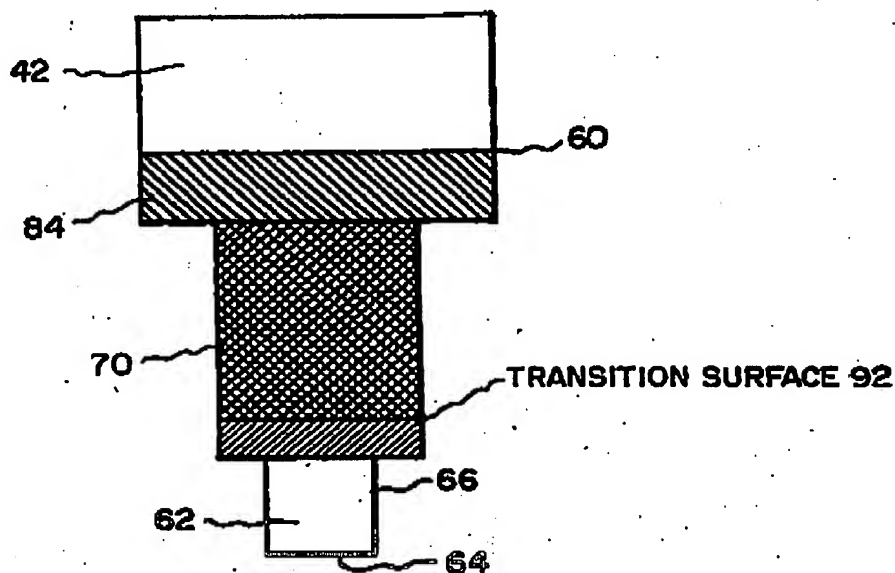


Figure 9A

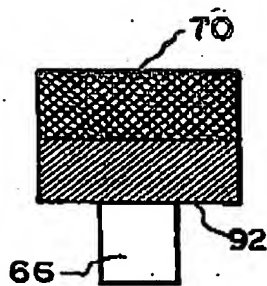


Figure 9B

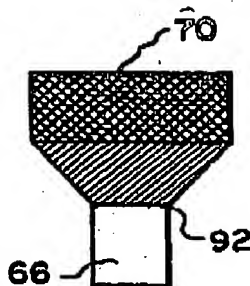


Figure 9C

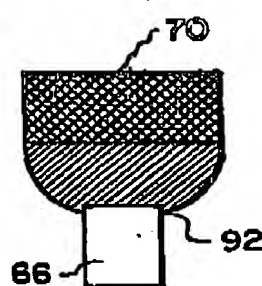


Figure 9D

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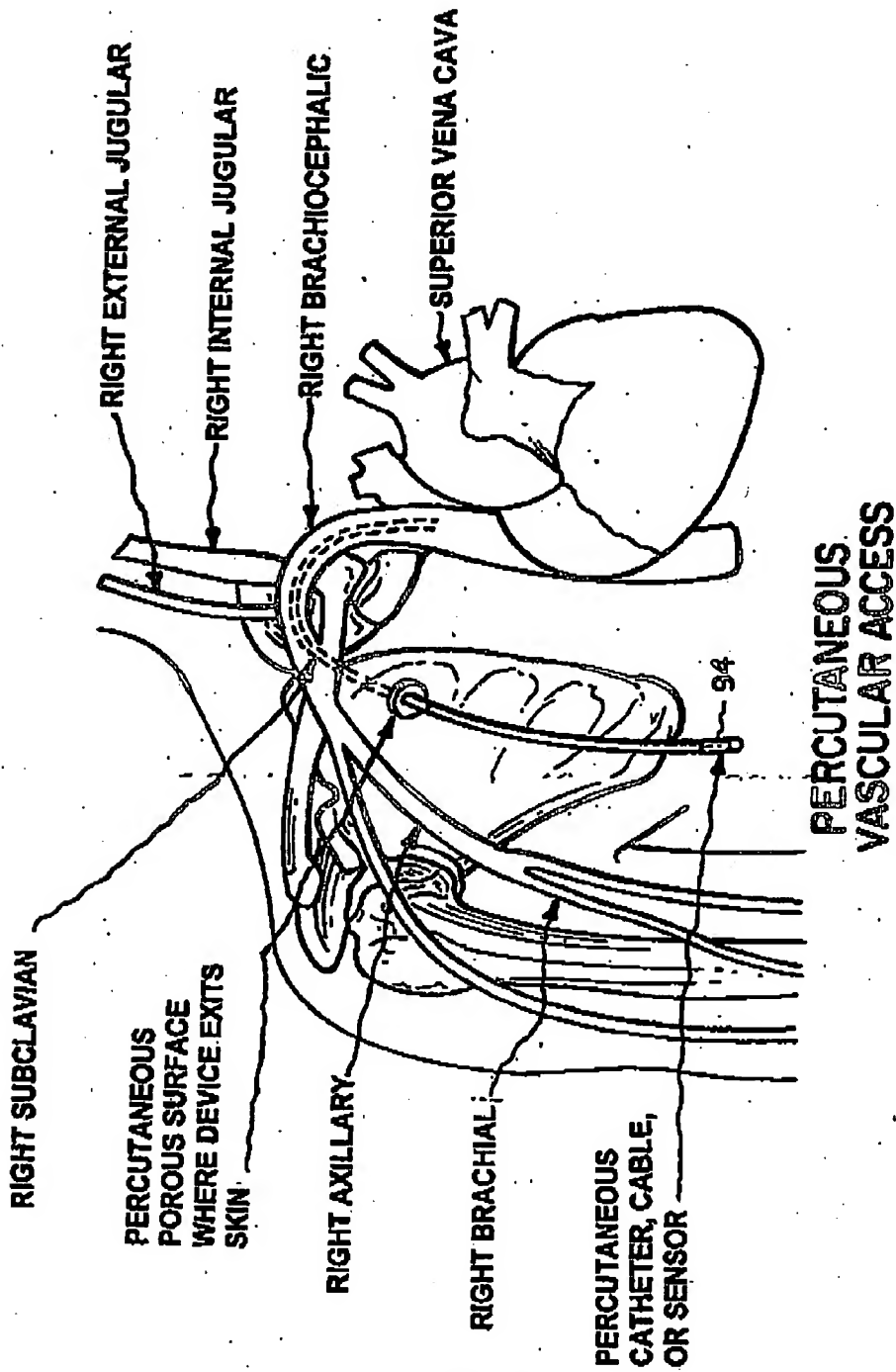


Figure 10

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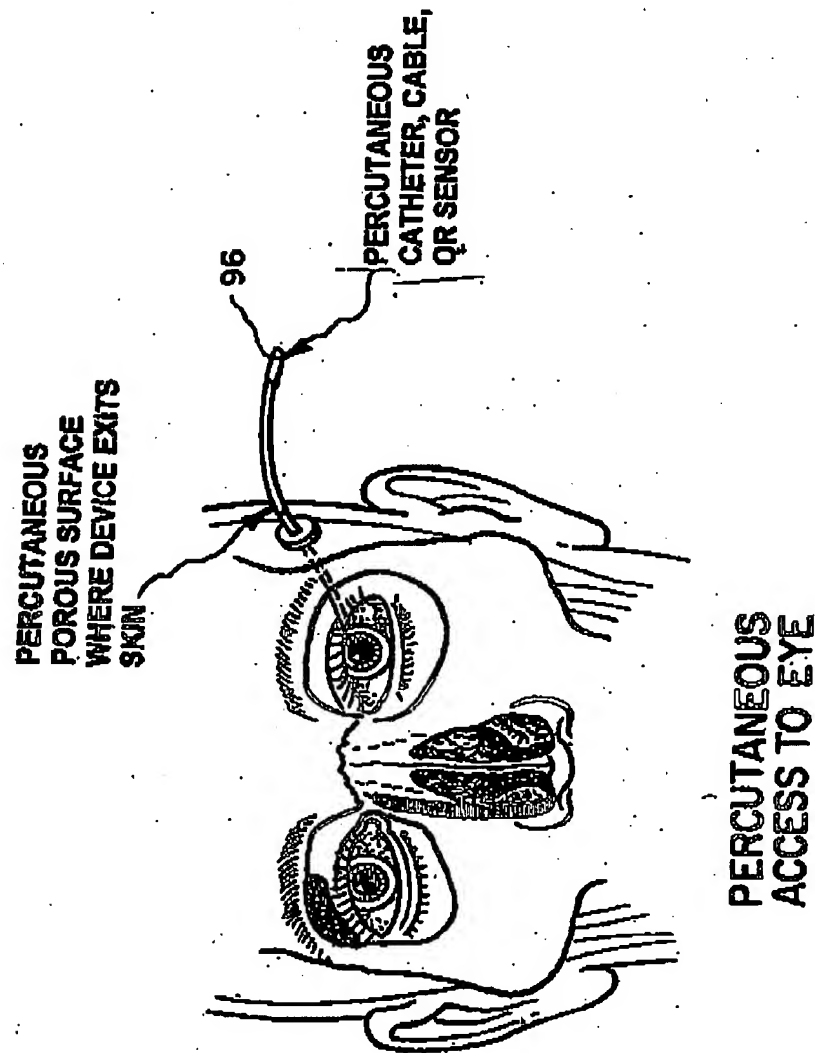


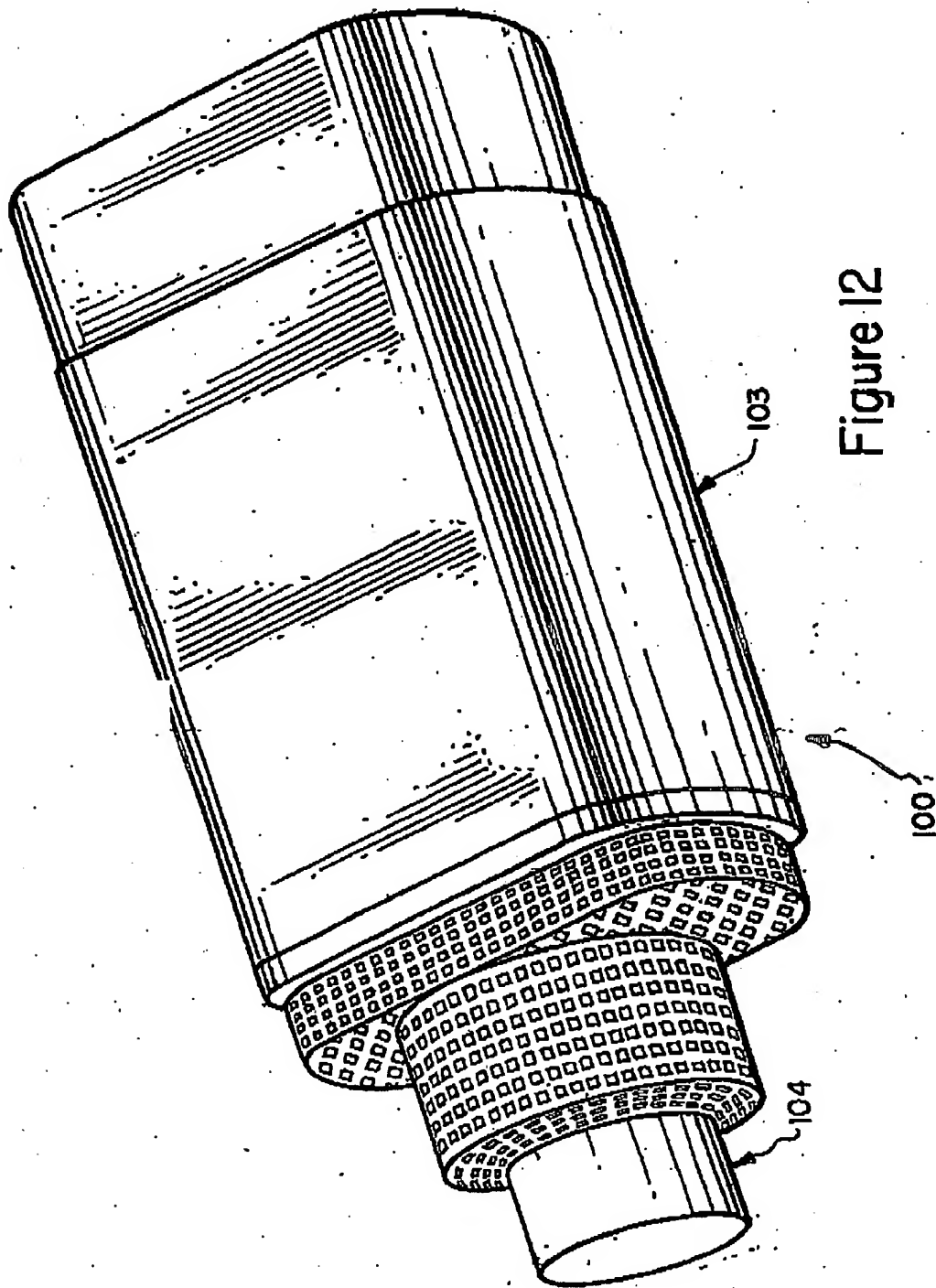
Figure 11

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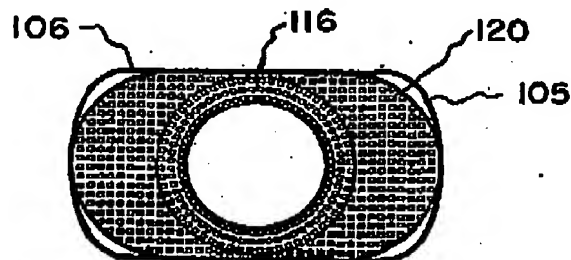


Figure 13A

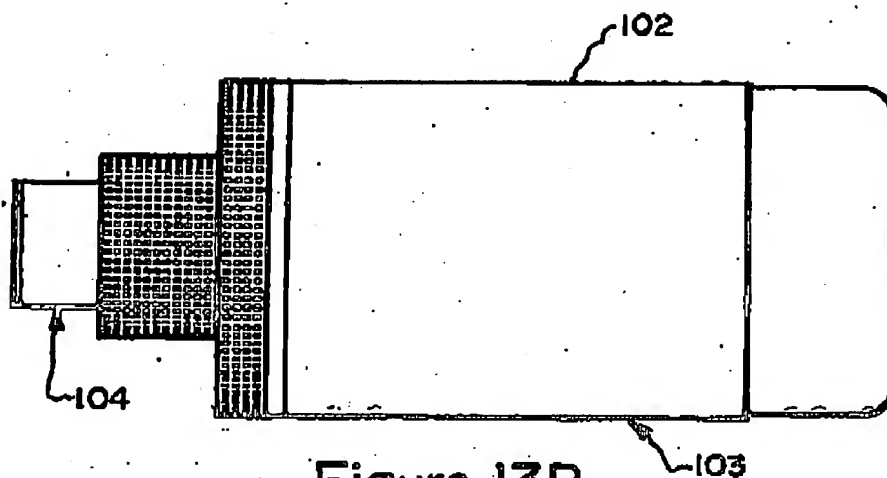


Figure 13B

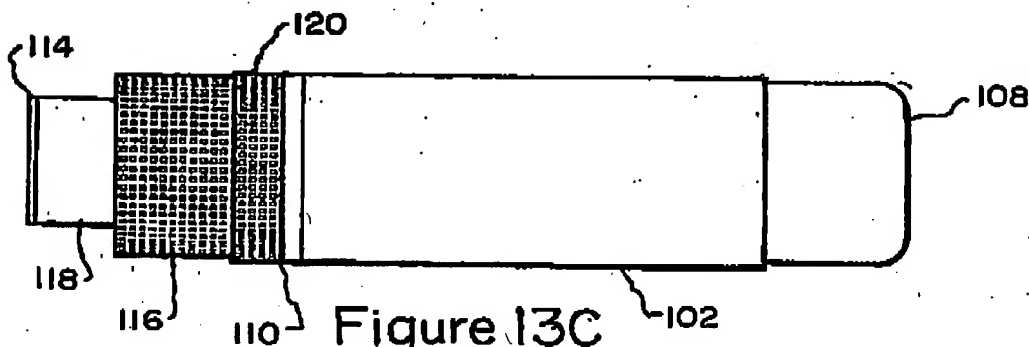


Figure 13C

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